

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/016091

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl<sup>7</sup> A61K31/48, A61K9/70, A61K47/32, A61P25/16

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl<sup>7</sup> A61K31/48, A61K9/70, A61K47/32, A61P25/16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CAPLUS (STN), CAOLD (STN), REGISTRY (STN), MEDLINE (STN), BIOSIS (STN), EMBASE (STN)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/38139 A1 (Hisamitsu Pharmaceutical Co., Inc.), 16 May, 2002 (16.05.02), Full text; particularly, Claims; pages 1, 5 to 10; example 5 & EP 1340496 A1 & US 2004/0028724 A & AU 200196029 A	1-12
X	WO 03/013611 A1 (Hisamitsu Pharmaceutical Co., Inc.), 20 February, 2003 (20.02.03), Full text; particularly, Claims; pages 2, 4 to 9; examples 1, 2 & EP 1421955 A1 & KR 2004029415 A & AU 2002328603 A1	1-12

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search  
10 December, 2004 (10.12.04)

Date of mailing of the international search report  
28 December, 2004 (28.12.04)

Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/016091

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/69942 A1 (Hisamitsu Pharmaceutical Co., Inc.), 12 September, 2002 (12.09.02), Full text; particularly, Claims; pages 2, 5 to 15; examples 3, 4 & EP 1366762 A1 & US 2004/0096491 A1 & KR 2003080070 A & BR 200207955 A & AU 2002236252 A & CN 1499962 A	1-12
X	WO 03/013613 A1 (Hisamitsu Pharmaceutical Co., Inc.), 20 February, 2003 (20.02.03), Full text; particularly, Claims; pages 1, 6 to 12; examples 4, 5 & EP 1447097 A1 & AU 2002328602 A	1-12
X	JP 2000-514053 A (Hexal AG.), 24 October, 2000 (24.10.00), Full text; particularly, Claims; page 5; examples & WO 98/00142 A1 & EP 910379 A1 & US 6623752 B1 & AU 9736926 A & DE 19626621 A	1-12
X	JP 2002-515424 A (Schwarz Pharma AG.), 28 May, 2002 (28.05.02), Full text; particularly, Claims; examples & WO 99/59558 A1 & EP 1077688 A1 & US 6461636 B1 & AU 9940407 A & NO 200004859 A & BR 9910404 A & ZA 200004670 A & CN 1301152 A & KR 2001042685 A	1-12
A	WONG, D.T. et al., Dopamine receptor affinities in vitro and neurochemical effects in vivo of pergolide and its metabolites, Arzneimittel-Forschung, 1993, Vol.43, No.4, pages 409 to 412	1-12
A	CLEMENS, J.A. et al., Dopamine agonist activities of pergolide, its metabolites, and bromocriptine as measured by prolactin inhibition, compulsive turning, and stereotypic behavior, Arzneimittel-Forschung, 1993, Vol.43, No.3, pages 281 to 286	1-12
P,X	JP 2004-83523 A (Hisamitsu Pharmaceutical Co., Inc.), 18 March, 2004 (18.03.04), Full text; particularly, Claims; pages 5 to 10; examples & WO 04/019988 A1 & AU 200354875 A	1-12

## INTERNATIONAL SEARCH REPORT

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PCT/JP2004/016091

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	JP 2004-83520 A (Hisamitsu Pharmaceutical Co., Inc.), 18 March, 2004 (18.03.04), Full text; particularly, Claims; pages 7 to 11; examples & WO 04/19987 A1 & AU 2003254874 A	1-12

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/JP2004/016091

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:  
(See extra sheet.)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

International application No.

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Continuation of Box No.III of continuation of first sheet(2)

The matter common to the inventions according to claims 1 to 12 resides in a transdermal preparation containing pergolide and/or a pharmaceutically acceptable salt thereof.

As the results of the search, however, it is found out that a transdermal preparation containing pergolide and/or a pharmaceutically acceptable salt thereof is not novel because of having been disclosed in documents WO 02/38139 A1 (Hisamitsu Pharmaceutical Co., Inc.) 16 May, 2002 (16.05.02), WO 03/013611 A1 (Hisamitsu Pharmaceutical Co., Inc.) 20 February, 2003 (20.02.03) and so on.

Accordingly, a transdermal preparation containing pergolide and/or a pharmaceutically acceptable salt thereof falls within the category of prior art and, therefore, the above common matter cannot be referred to as a special technical feature in the meaning within the second sentence of PCT Rule 13.2.

Thus, there is no matter common to all of the inventions according to claims 1 to 12.

Since there is no other common matter seemingly being a special technical feature in the meaning within the second sentence of PCT Rule 13.2, no technical relevancy can be found between these groups of inventions differing from each other in the meaning within PCT Rule 13.

Such being the case, it is obvious that the inventions according to claims 1 to 12 do not comply with the requirement of unity of invention.

It is recognized that claims 1 to 12 have the following two groups of inventions.

1) The transdermal preparation containing pergolide and/or a pharmaceutically acceptable salt thereof as set forth in claims 1 to 10 and 12, which is capable of achieving a plasma AUC ratio of pergolide or the like to at least one metabolite thereof of 1:0.5 to 1:5.

2) The transdermal preparation containing pergolide and/or a pharmaceutically acceptable salt thereof as set forth in claim 11, which is capable of achieving a ratio (A/B) of the maximum plasma level (A) of pergolide and/or a pharmaceutically acceptable salt thereof to the plasma level (B) thereof in the next administration, and or the ratio (A'/B') of the maximum plasma level (A') of pergolide sulfoxide to the plasma level (B') of pergolide sulfoxide in the next administration of less than 2.

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